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BIOSIMILAR BIOLOGICAL PRODUCT AUTHORIZATION PERFORMANCE GOALS AND PROCEDURES FOR FISCAL YEARS 2018 THROUGH 2022

This document contains the performance goals and procedures for the Biosimilar Biological Product User Fee Act (BsUFA) reauthorization for fiscal years (FYs) 2018-2022, known as BsUFA II. It is commonly referred to as the "goals letter" or "commitment letter." The goals letter represents the product of FDA's discussions with the regulated industry and public stakeholders, as mandated by Congress. The performance and procedural goals and other commitments specified in this letter apply to aspects of the biosimilar biological product review program that are important for facilitating timely access to safe and effective biosimilar medicines for patients. FDA is committed to meeting the performance goals specified in this letter, enhancing management of BsUFA resources, and ensuring BsUFA user fee resources are administered, allocated, and reported in an efficient and transparent manner.

Under BsUFA II, FDA is committed to ensuring effective scientific coordination and review consistency, as well as efficient governance and operations across the biosimilar biological product review program. In addition, FDA is committed to the principles articulated in the Good Review Management Principles and Practices (GRMP) guidance[1], which FDA intends to update and apply to the review of biosimilar and interchangeable products.

FDA and the regulated industry will periodically and regularly assess the progress of the biosimilar biological product review program throughout BsUFA II. This will allow FDA and the regulated industry to identify emerging challenges and develop strategies to address these challenges to ensure the efficiency and effectiveness of the biosimilar biological product review program.

[1] Refer to the Good Review Management Principles and Practices for PDUFA Products guidance (hereinafter referred to as 'GRMP guidance') available at http://www.fda.gov/downloads/Drugs/.../Guidances/ucm079748.pdf

I. ENSURING THE EFFECTIVNESS OF THE BIOSIMILAR BIOLOGICAL PRODUCT REVIEW PROGRAM

A. REVIEW PERFORMANCE GOALS

1. Biosimilar Biological Product Application Submissions and Resubmissions

a. Review and act on 90 percent of original biosimilar biological product application submissions within 10 months of the 60 day filing date.

b. Review and act on 90 percent of resubmitted original biosimilar biological product applications within 6 months of receipt.

2. Supplements with Clinical Data

a. Review and act on 90 percent of original supplements with clinical data within 10 months of receipt.

b. Review and act on 90 percent of resubmitted supplements with clinical data within 6 months of receipt.

3. Original Manufacturing Supplements

a. In FY 2018, review and act on 70 percent of manufacturing supplements requiring prior approval within 4 months of receipt.

b. In FY 2019, review and act on 75 percent of manufacturing supplements requiring prior approval within 4 months of receipt.

c. In FY 2020, review and act on 80 percent of manufacturing supplements requiring prior approval within 4 months of receipt.

d. In FY 2021, review and act on 85 percent of manufacturing supplements requiring prior approval within 4 months of receipt.

e. In FY 2022, review and act on 90 percent of manufacturing supplements requiring prior approval within 4 months of receipt.

f. Review and act on 90 percent of all other manufacturing supplements within 6 months of receipt

4. Goals Summary Tables

Table 1: Original and Resubmitted Applications and Supplements

Original Biosimilar Biological Product Application Submissions	90% in 10 months of the 60 day filing date
Resubmitted Original Biosimilar Biological Product Applications	90% in 6 months of the receipt date
Original Supplements with Clinical Data	90% in 10 months of the receipt date
Resubmitted Supplements with Clinical Data	90% in 6 months of the receipt date

Table 2: Manufacturing Supplements

	PRIOR APPROVAL	**ALL OTHER**
Manufacturing Supplements	• FY 2018: 70% in 4 months of the receipt date • FY 2019: 75% in 4 months of the receipt date • FY 2020: 80% in 4 months of the receipt date • FY 2021: 85% in 4 months of the receipt date • FY 2022: 90% in 4 months of the receipt date	90% in 6 months of the receipt date

5. Review Performance Goal Extensions

a. Major Amendments

i. A major amendment to an original application, supplement with clinical data, or resubmission of any of these applications, submitted at any time during the review cycle, may extend the goal date by three months.

ii. A major amendment may include, for example, a major new clinical study report; major re-analysis of previously submitted study(ies); submission of a risk evaluation and mitigation strategy (REMS) with elements to assure safe use (ETASU) not included in the original application; or significant amendment to a previously submitted REMS with ETASU. Generally, changes to REMS that do not include ETASU and minor changes to REMS with ETASU will not be considered major amendments.

iii. A major amendment to a manufacturing supplement submitted at any time during the review cycle may extend the goal date by two months.

iv. Only one extension can be given per review cycle.

v. Consistent with the underlying principles articulated in the GRMP guidance, FDA's decision to extend the review clock should, except in rare circumstances, be limited to occasions where review of the new information could address outstanding deficiencies in the application and lead to approval in the current review cycle.

b. Inspection of Facilities Not Adequately Identified in an Original Application or Supplement

i. All original applications and supplements are expected to include a comprehensive and readily located list of all manufacturing facilities included or referenced in the application or supplement. This list provides FDA with information needed to schedule inspections of manufacturing facilities that may be necessary before approval of the original application or supplement.

ii. If, during FDA's review of an original application or supplement, the Agency identifies a manufacturing facility that was not included in the comprehensive and readily located list, the goal date may be extended.

1. If FDA identifies the need to inspect a manufacturing facility that is not included as part of the comprehensive and readily located list in an original application or supplement with clinical data, the goal date may be extended by three months.

2. If FDA identifies the need to inspect a manufacturing facility that is not included as part of the comprehensive and readily located list in a manufacturing supplement, the goal date may be extended by two months.

B. PROGRAM FOR ENHANCED REVIEW TRANSPARENCY AND COMMUNICATION FOR ORIGINAL 351(k) BLAs

To promote transparency and communication between the FDA review team and the applicant, FDA will apply the following model ("the Program") to the review of all original Biologics License Applications (BLAs) submitted under section 351(k) of the Public Health Service Act ("351(k) BLAs"), including applications that are resubmitted following a Refuse-to-File decision, received from October 1, 2017, through September 30, 2022.[2] The goal of the Program is to promote the efficiency and effectiveness of the first cycle review process and minimize the number of review cycles necessary for approval, ensuring that patients have timely access to safe, effective, and high quality biosimilar and interchangeable biological products.

The standard approach for the review of original 351(k) BLAs is described in this section. However, the FDA review team and the applicant may discuss and reach mutual agreement on an alternative approach to the timing and nature of interactions and information exchange between the applicant and FDA, i.e., a Formal Communication Plan for the review of the original 351(k) BLA. The Formal Communication Plan may include elements of the standard approach (e.g., a mid-cycle communication or a late-cycle meeting) as well as other interactions that sometimes occur during the review process (e.g., a meeting during the filing period to discuss the application, i.e., an "application orientation meeting"). If appropriate, the Formal Communication Plan should specify those elements of the Program that FDA and the sponsor agree are unnecessary for the application under review. If the review team and the applicant anticipate developing a Formal Communication Plan, the elements of the plan should be discussed and agreed to at the pre-submission meeting (see Section I.B.1) and reflected in the meeting minutes. The Formal Communication Plan may be reviewed and amended at any time based on the progress of the review and the mutual agreement of the review team and the applicant. For example, the review team and the applicant may mutually agree at any time to cancel future specified interactions in the Program (e.g., the late-cycle meeting) that become unnecessary

[2] The "Program for Enhanced Review Transparency and Communication for Original 351(k) BLAs" (referred to as "the Program" and described in this goals letter) is distinct from the statutory term, "biosimilar biological product development program," which is defined in section 744G of the Federal Food, Drug, and Cosmetic (FD&C Act) as "the program under [the statutory BsUFA fee provisions] for expediting the process for the review of submissions in connection with biosimilar biological product development." Section 744G(6) of the FD&C Act.

(e.g. because previous communications between the review team and the applicant are sufficient). Any amendments made to the Formal Communication Plan should be consistent with the goal of an efficient and timely first cycle review process and not impede the review team's ability to conduct its review.

The remainder of this Section I.B. describes the parameters that will apply to FDA's review of applications in the Program.

1. **Pre-submission meeting:** The applicant is strongly encouraged to discuss the planned content of the application with the appropriate FDA review division at a BPD Type 4 (pre-351(k) BLA) meeting. This meeting will be attended by the FDA review team, including appropriate senior FDA staff.

    a. The BPD Type 4 (pre-351(k) BLA) meeting should be held sufficiently in advance of the planned submission of the application to allow for meaningful response to FDA feedback and should generally occur not less than 2 months prior to the planned submission of the application.

    b. In addition to FDA's preliminary responses to the applicant's questions, other potential discussion topics include preliminary discussions regarding the approach to developing the content for REMS, where applicable, patient labeling (e.g., Medication Guide and Instructions For Use) and, where applicable, the development of a Formal Communication Plan. These discussions will be summarized at the conclusion of the meeting and reflected in the FDA meeting minutes.

        The FDA and the applicant will agree on the content of a complete application for the proposed indication(s) at the pre-submission meeting. The FDA and the applicant may also reach agreement on submission of a limited number of application components not later than 30 calendar days after the submission of the original application. These submissions must be of a type that would not be expected to materially impact the ability of the review team to begin its review. These agreements will be summarized at the conclusion of the meeting and reflected in the FDA meeting minutes.

        i. Examples of application components that may be appropriate for delayed submission include; stability updates, the final audited report of a preclinical study (e.g., toxicology) where the final draft report is submitted with the original application, or a limited amount of the data from an assessment of a single transition from the reference product to the proposed biosimilar biological product, where applicable.

        ii. Major components of the application (e.g., the complete analytical similarity assessment, the complete study report of a comparative clinical study or the full study report of necessary immunogenicity

data) are expected to be submitted with the original application and are not subject to agreement for late submission.

2. **Original application submission:** Applications are expected to be complete, as agreed between the FDA review team and the applicant at the BPD Type 4 (pre-351(k) BLA) meeting, at the time of original submission of the application. If the applicant does not have a BPD Type 4 (pre-351(k) BLA) meeting with FDA, and no agreement exists between FDA and the applicant on the contents of a complete application or delayed submission of certain components of the application, the applicant's submission is expected to be complete at the time of original submission.

   a. All applications are expected to include a comprehensive and readily located list of all clinical sites and manufacturing facilities included or referenced in the application.

   b. Any components of the application that FDA agreed at the pre-submission meeting could be submitted after the original application are expected to be received not later than 30 calendar days after receipt of the original application.

   c. Incomplete applications, including applications with components that are not received within 30 calendar days after receipt of the original submission, will be subject to a Refuse-to-File decision.

   d. The following parameters will apply to applications that are subject to a Refuse-to-File decision and are subsequently filed over protest:

      i. The original submission of the application will be subject to the review performance goal as described in Section I.A.1.a.

      ii. The application will not be eligible for the other parameters of the Program (e.g., mid-cycle communication, late-cycle meeting).

      iii. FDA generally will not review amendments to the application during any review cycle. FDA also generally will not issue information requests to the applicant during the agency's review.

      iv. The resubmission goal described in Section I.A.1.b will not apply to any resubmission of the application following an FDA complete response action. Any such resubmission will be reviewed as available resources permit.

   e. Since applications are expected to be complete at the time of submission, unsolicited amendments are expected to be rare and not to contain major new information or analyses. Review of unsolicited amendments, including those submitted in response to an FDA communication of deficiencies, will be handled in accordance with the GRMP guidance. This guidance includes the underlying principle that FDA will consider the

most efficient path toward completion of a comprehensive review that addresses application deficiencies and leads toward a first cycle approval when possible.

3. **Day 74 Letter:** FDA will follow existing procedures regarding identification and communication of substantive review issues identified during the initial filing review to the applicant in the "Day 74 letter." If no substantive review issues were identified during the filing review, FDA will so notify the applicant. FDA's filing review represents a preliminary review of the application and is not indicative of deficiencies that may be identified later in the review cycle.

   For applications subject to the Program, the timeline for this communication will be within 74 calendar days from the date of FDA receipt of the original submission. The planned timeline for review of the application included in the Day 74 letter for applications in the Program will include:

   a. the planned date for the internal mid-cycle review meeting,

   b. preliminary plans on whether to hold an Advisory Committee (AC) meeting to discuss the application,

   c. a target date for communication of feedback from the review division to the applicant regarding proposed labeling and any postmarket requirements or postmarket commitments the Agency will be requesting.

4. **Review performance goals:** For original 351(k) BLA submissions that are filed by FDA under the Program, the BsUFA review clock will begin at the conclusion of the 60 calendar day filing review period that begins on the date of FDA receipt of the original submission. The review performance goals for these applications are as follows:

   a. Review and act on 90 percent of original 351(k) BLA submissions within 10 months of the 60 day filing date.

5. **Mid-Cycle Communication:** The FDA Regulatory Project Manager (RPM), and other appropriate members of the FDA review team (e.g., Cross Discipline Team Leader (CDTL)), will call the applicant, generally within 2 weeks following the Agency's internal mid-cycle review meeting, to provide the applicant with an update on the status of the review of their application. An agenda will be sent to the applicant prior to the mid-cycle communication. Scheduling of the internal mid-cycle review meeting will be handled in accordance with the GRMP guidance. The RPM will coordinate the specific date and time of the telephone call with the applicant.

The update should include any significant issues identified by the review team to date, any information requests, and information regarding major concerns with the following:

a. The analytical similarity data, including the potential relevance of any issues (e.g. data analysis issues or potential clinical impact of observed analytical differences), intended to support a demonstration that the proposed biosimilar biological product is highly similar to the reference product.

b. The data intended to support a demonstration of no clinically meaningful differences, including discussion of any immunogenicity issues.

c. The data intended to support a demonstration of interchangeability.

d. CMC issues.

In addition, the update should include preliminary review team thinking regarding the content of the proposed REMS, where applicable, proposed date(s) for the late-cycle meeting, updates regarding plans for the AC meeting (if an AC meeting is anticipated), and other projected milestone dates for the remainder of the review cycle.

6. **Late-Cycle and Advisory Committee Meetings:** A meeting will be held between the FDA review team and the applicant to discuss the status of the review of the application late in the review cycle. Late-cycle meetings will generally be face-to-face meetings; however, the meeting may be held by teleconference if FDA and the applicant agree. Since the application is expected to be complete at the time of submission, FDA intends to complete primary and secondary reviews of the application in advance of the planned late-cycle meeting.

   a. FDA representatives at the late-cycle meeting are expected to include the signatory authority for the application, review team members from appropriate disciplines, and appropriate team leaders and/or supervisors from disciplines for which substantive issues have been identified in the review to date.

   b. For applications that will be discussed at an Advisory Committee (AC) meeting, the following parameters apply:

      i. FDA intends to convene AC meetings no later than 2 months prior to the BsUFA goal date. The late-cycle meeting will occur not less than 12 calendar days before the date of the AC meeting.

      ii. FDA intends to provide final questions for the AC to the sponsor and the AC not less than 2 calendar days before the AC meeting.

iii. Following an AC meeting, FDA and the applicant may agree on the need to discuss feedback from the committee for the purpose of facilitating the remainder of the review. Such a meeting will generally be held by teleconference without a commitment for formal meeting minutes issued by the agency.

c. For applications that will not be discussed at an AC meeting, the late-cycle meeting will generally occur not later than 3 months prior to the BsUFA goal date.

d. Late-Cycle Meeting Background Packages: The Agency background package for the late-cycle meeting will be sent to the applicant not less than 10 calendar days before the late-cycle meeting. The package will consist of any discipline review (DR) letters issues to date, a brief memorandum from the review team outlining substantive application issues (e.g., deficiencies identified by primary and secondary reviews), the Agency's background package for the AC meeting (incorporated by reference if previously sent to the applicant), potential questions and/or points for discussion for the AC meeting (if planned) and the current assessment of the content of proposed REMS or other risk management actions, where applicable.

e. Late-Cycle Meeting Discussion Topics: Potential topics for discussion at the late-cycle meeting include:

i. major deficiencies identified to date;

ii. analytical similarity data, including the potential relevance of any issues (e.g. data analysis issues or potential clinical impact of observed analytical differences), intended to support a demonstration that the proposed biosimilar biological product is highly similar to the reference product;

iii. data intended to support a demonstration of no clinically meaningful differences, including discussion of any immunogenicity issues;

iv. data intended to support a demonstration of interchangeability;

v. CMC issues;

vi. inspectional findings identified to date;

vii. issues to be discussed at the AC meeting (if planned);

viii. current assessment of the content of proposed REMS or other risk management actions, where applicable;

ix. information requests from the review team to the applicant; and additional data or analyses the applicant may wish to submit.

With regard to submission of additional data or analyses, the FDA review team and the applicant will discuss whether such data will be reviewed by

the Agency in the current review cycle and, if so, whether the submission will be considered a major amendment and trigger an extension of the BsUFA goal date.

7. **Inspections:** FDA's goal is to complete all GCP, GLP, and GMP inspections for applications in the Program within 10 months of the date of original receipt of the application. This will allow 2 months at the end of the review cycle to attempt to address any deficiencies identified by the inspections.

8. **Assessment of the Program:** The Program described in this Section I.B shall be evaluated to determine its impact on the efficiency and effectiveness of the first review cycle for biosimilar biological products. The assessment shall be conducted by an independent contractor with expertise in assessing the quality and efficiency of biopharmaceutical development and regulatory review programs. The statement of work for this effort will be published for public comment prior to beginning the assessment. The assessments will occur continuously throughout the course of the Program.

   Aspects and other measures of the Program that will be assessed by the independent contractor include, but are not limited to the following:

   - adherence by the applicant and FDA to the current GRMP guidance or the GRMP guidance as updated in accordance with Section I.D, as applicable
   - completeness and quality of the submitted application
   - number of unsolicited amendments submitted by the applicant
   - timing and adequacy of Day 74 letters
   - conduct of the mid-cycle communication
   - any DR letters issued
   - late-cycle meeting background package
   - conduct of the late-cycle meeting
   - time to approval
   - percentage of applications that are approved during the first review cycle
   - percentage of application reviews that are extended due to a major amendment
   - number of review cycles for applications that are ultimately approved

- time to resubmission for applications that receive a complete response in the first review cycle

This assessment will also include a de-identified analysis of the issues typically discussed during the mid-cycle communication and the late-cycle meeting and the ability of the additional FDA-applicant communications to (a) achieve resolution of these issues during the remainder of the review clock, or (b) allow the applicant to better prepare for a resubmission of the application. Following an FDA regulatory action, the independent contractor will conduct separate interviews of the applicant and the FDA review team to understand each party's perspectives on the review of the application, including whether issues were or should have been identified at the BPD meetings to facilitate application review.

An interim and final assessment of the Program will be published for public comment, with each report followed by a public meeting during which public stakeholders may present their views on the success of the Program to date, including the ability of the Program to help ensure that patients have timely access to safe, effective, and high quality biosimilar biological products. During each public meeting, FDA and the independent contractor will discuss the findings of the interim assessment, including anonymized aggregated feedback from sponsors and FDA review teams resulting from independent contractor interviews. FDA will discuss any issues identified to date including any proposed plans to improve the likelihood of the Program's success.

a. Interim Assessment: An interim assessment of the Program will be published by December 31, 2020, and FDA will hold a public meeting by March 31, 2021.

b. Final Assessment: A final assessment of the Program will be published by June 30, 2022, and FDA will hold a public meeting by September 30, 2022.

C. FIRST CYCLE REVIEW MANAGEMENT FOR SUPPLEMENTS WITH CLINICAL DATA

1. Notification of Issues Identified during the Filing Review

a. Performance Goal: For supplements with clinical data, FDA will report substantive review issues identified during the initial filing review to the applicant by letter.

b. The timeline for such communication will be within 74 calendar days from the date of FDA receipt of the supplement.

c. If no substantive review issues were identified during the filing review, FDA will so notify the applicant.

d. FDA's filing review represents a preliminary review of the application and is not indicative of deficiencies that may be identified later in the review cycle.

e. FDA will notify the applicant of substantive review issues prior to or on the goal date for 90% of applications.

2. Notification of Planned Review Timelines

a. Performance Goal: For supplements with clinical data, FDA will inform the applicant of the planned timeline for review of the application. The information conveyed will include a target date for communication of feedback from the review division to the applicant regarding proposed labeling, postmarketing requirements, and postmarketing commitments the Agency will be requesting.

b. The planned review timeline will be included with the notification of issues identified during the filing review, within 74 calendar days from the date of FDA receipt of the original supplement.

c. The planned review timelines will be consistent with the GRMP guidance.

d. The planned review timeline will be based on the supplement as submitted.

e. FDA will inform the applicant of the planned review timeline for 90% of all supplements with clinical data.

f. In the event FDA determines that significant deficiencies in the supplement preclude discussion of labeling, postmarketing requirements, or postmarketing commitments by the target date identified in the planned review timeline (e.g., significant safety concern(s), need for a new study(ies) or extensive re-analyses of existing data before approval), FDA will communicate this determination to the applicant in accordance with GRMPs and no later than the target date. In such cases the planned review timeline will be considered to have been met. Communication of FDA's determination may occur by letter, teleconference, facsimile, secure e-mail, or other expedient means.

g. To help expedite the development of biosimilar biological products, communication of the deficiencies identified in the supplement may occur through issuance of a DR letter(s) in advance of the planned target date for initiation of discussions regarding labeling, postmarketing requirements, and postmarketing commitments the Agency may request.

f. If the applicant submits a major amendment(s) (refer to Section I.A.5.a for additional information on major amendments) and the review division chooses to review such amendment(s) during that review cycle, the planned review timeline initially communicated (under Section I.C.2.a and b) will generally no longer be applicable. Review of unsolicited amendments, including those submitted in response to an FDA communication of deficiencies, will be handled in accordance with the GRMP guidance. This guidance includes the underlying principle that FDA will consider the most efficient path toward completion of a comprehensive review that addresses supplement deficiencies and leads toward a first cycle approval when possible.

D. GUIDANCE

FDA and industry share a commitment to ensuring an efficient and effective first cycle review process for all applications subject to the BsUFA program. This commitment is consistent with the principles articulated in the GRMP guidance, which FDA applies to the review of biosimilar and interchangeable products. FDA will update the GRMP guidance during BsUFA II to ensure that it encompasses all review activities for biosimilar and interchangeable products, including principles regarding notification to applicants regarding issues identified during FDA's initial review of the application, principles regarding FDA's notification to applicants regarding planned review timelines, and the importance of internal review timelines that govern aspects of biosimilar and interchangeable product review that are not part of BsUFA performance goals. FDA will publish a revised draft guidance for public comment no later than the end of FY 2018. FDA will work toward the goal of publishing a revised draft or final guidance within 18 months after the close of the public comment period.

E. REVIEW OF PROPRIETARY NAMES TO REDUCE MEDICATION ERRORS

To enhance patient safety, FDA is committed to various measures to reduce medication errors related to look-alike and sound-alike proprietary names and such factors as unclear label abbreviations, acronyms, dose designations, and error prone label and packaging design. The following performance goals apply to FDA's review of biosimilar biological product proprietary names during the biosimilar biological product development (BPD) phase and during FDA's review of a marketing application:

1. **Proprietary Name Review Performance Goals During The BPD Phase**

    a. Review 90% of proprietary name submissions filed within 180 days of receipt. Notify sponsor of tentative acceptance or non-acceptance.

    b. If the proprietary name is found to be unacceptable, the sponsor can request reconsideration by submitting a written rebuttal with supporting data or request a meeting within 60 days to discuss the initial decision (meeting package required).

    c. If the proprietary name is found to be unacceptable, the above review performance goals also would apply to the written request for reconsideration with supporting data or the submission of a new proprietary name.

    d. A complete submission is required to begin the review clock.

2. **Proprietary Name Review Performance Goals During Application Review**

    a. Review 90% of biosimilar biological product proprietary name submissions filed within 90 days of receipt. Notify sponsor of tentative acceptance/non-acceptance.

    b. A supplemental review will be done meeting the above review performance goals if the proprietary name has been submitted previously (during the BPD phase) and has received tentative acceptance.

    c. If the proprietary name is found to be unacceptable, the sponsor can request reconsideration by submitting a written rebuttal with supporting data or request a meeting within 60 days to discuss the initial decision (meeting package required).

    d. If the proprietary name is found to be unacceptable, the above review performance goals apply to the written request for reconsideration with supporting data or the submission of a new proprietary name.

    e. A complete submission is required to begin the review clock.

F. MAJOR DISPUTE RESOLUTION

1. **Procedure:** For procedural or scientific matters involving the review of biosimilar biological product applications and supplements (as defined in BsUFA) that cannot be resolved at the signatory authority level (including a request for reconsideration by the signatory authority after reviewing any

materials that are planned to be forwarded with an appeal to the next level), the response to appeals of decisions will occur within 30 calendar days of the Center's receipt of the written appeal.

2. **Performance goal:** 90% of such responses are provided within 30 calendar days of the Center's receipt of the written appeal.

3. **Conditions:**

   a. Sponsors should first try to resolve the procedural or scientific issue at the signatory authority level. If it cannot be resolved at that level, it should be appealed to the next higher organizational level (with a copy to the signatory authority) and then, if necessary, to the next higher organizational level.

   b. Responses should be either verbal (followed by a written confirmation within 14 calendar days of the verbal notification) or written and should ordinarily be to either grant or deny the appeal.

   c. If the decision is to deny the appeal, the response should include reasons for the denial and any actions the sponsor might take to persuade the Agency to reverse its decision.

   d. In some cases, further data or further input from others might be needed to reach a decision on the appeal. In these cases, the "response" should be the plan for obtaining that information (e.g., requesting further information from the sponsor, scheduling a meeting with the sponsor, scheduling the issue for discussion at the next scheduled available advisory committee).

   e. In these cases, once the required information is received by the Agency (including any advice from an advisory committee), the person to whom the appeal was made, again has 30 calendar days from the receipt of the required information in which to either deny or grant the appeal.

   f. Again, if the decision is to deny the appeal, the response should include the reasons for the denial and any actions the sponsor might take to persuade the Agency to reverse its decision.

   g. Note: If the Agency decides to present the issue to an advisory committee and there are not 30 days before the next scheduled advisory committee, the issue will be presented at the following scheduled committee meeting to allow conformance with advisory committee administrative procedures.

G. CLINICAL HOLDS

1. **Procedure:** The Center should respond to a sponsor's complete response to a clinical hold within 30 days of the Agency's receipt of the submission of such sponsor response.

2. **Performance goal:** 90% of such responses are provided within 30 calendar days of the Agency's receipt of the sponsor's response.

H. SPECIAL PROTOCOL QUESTION ASSESSMENT AND AGREEMENT

1. **Procedure:** Upon specific request by a sponsor (including specific questions that the sponsor desires to be answered), the Agency will evaluate certain protocols and related issues to assess whether the design is adequate to meet scientific and regulatory requirements identified by the sponsor.

    a. The sponsor should submit a limited number of specific questions about the protocol design and scientific and regulatory requirements for which the sponsor seeks agreement (e.g., are the clinical endpoints adequate to assess whether there are clinically meaningful differences between the proposed biosimilar biological product and the reference product).

    b. Within 45 days of Agency receipt of the protocol and specific questions, the Agency will provide a written response to the sponsor that includes a succinct assessment of the protocol and answers to the questions posed by the sponsor. If the Agency does not agree that the protocol design, execution plans, and data analyses are adequate to achieve the goals of the sponsor, the reasons for the disagreement will be explained in the response.

    c. Protocols that qualify for this program include any necessary clinical study or studies to prove biosimilarity and/or interchangeability (e.g., protocols for pharmacokinetics and pharmacodynamics studies, protocols for comparative clinical studies that will form the primary basis for demonstrating that there are no clinically meaningful differences between the proposed biosimilar biological product and the reference product, and protocols for clinical studies intended to support a demonstration of interchangeability). For such protocols to qualify for this comprehensive protocol assessment, the sponsor must have had a BPD Type 2 or 3 Meeting, as defined in section I.I, below, with the review division so that the division is aware of the developmental context in which the protocol is being reviewed and the questions being answered.

    d. If a protocol is reviewed under the process outlined above, and agreement with the Agency is reached on design, execution, and analyses, and if the results of the trial conducted under the protocol substantiate the hypothesis

of the protocol, the Agency agrees that the data from the protocol can be used as part of the primary basis for approval of the product. The fundamental agreement here is that having agreed to the design, execution, and analyses proposed in protocols reviewed under this process, the Agency will not later alter its perspective on the issues of design, execution, or analyses unless public health concerns unrecognized at the time of protocol assessment under this process are evident.

2. **Performance goal:** 90% of special protocols assessments and agreement requests completed and returned to sponsor within 45 days.

3. **Reporting:** The Agency will track and report the number of original special protocol assessments and resubmissions per original special protocol assessment.

I. MEETING MANAGEMENT GOALS

Formal BsUFA meetings between sponsors and FDA consist of Biosimilar Initial Advisory and BPD Type 1-4 meetings. These meetings are further described below.

- A Biosimilar Initial Advisory Meeting is an initial assessment limited to a general discussion regarding whether licensure under section 351(k) of the Public Health Service Act may be feasible for a particular product, and, if so, general advice on the expected content of the development program. Such term does not include any meeting that involves substantive review of summary data or full study reports.

- A BPD Type 1 Meeting is a meeting which is necessary for an otherwise stalled drug development program to proceed (e.g. meeting to discuss clinical holds, dispute resolution meeting), a special protocol assessment meeting, or a meeting to address an important safety issue.

- A BPD Type 2 Meeting is a meeting to discuss a specific issue (e.g., proposed study design or endpoints) or questions where FDA will provide targeted advice regarding an ongoing biosimilar biological product development program. Such term may include substantive review of summary data, but does not include review of full study reports.

- A BPD Type 3 Meeting is an in depth data review and advice meeting regarding an ongoing biosimilar biological product development program. Such term includes substantive review of full study reports, FDA advice regarding the similarity between the proposed biosimilar biological product and the reference product, and FDA advice regarding additional studies, including design and analysis.

- A BPD Type 4 Meeting is a pre-submission meeting to discuss the format and content of a complete application for an original biosimilar biological product application under the Program or supplement submitted under 351(k) of the PHS Act. The purpose of this meeting is to discuss the format and content of the planned submission and other items, including identification of those studies that the sponsor is relying on to support a demonstration of biosimilarity or interchangeability, discussion of any potential review issues identified based on the information provided, identification of the status of ongoing or needed studies to adequately to address the Pediatric Research Equity Act (PREA), acquainting FDA reviewers with the general information to be submitted in the marketing application (including technical information), and discussion of the best approach to the presentation and formatting of data in the marketing application.

1. Response to Meeting Requests

a. Procedure**:** FDA will notify the requester in writing of the date, time, and place for the meeting, as well as expected Center participants following receipt of a formal meeting request and background package. Table 1 below indicates the timeframes for FDA's response to a meeting request.

Table 1:

Meeting Type	Response Time (calendar days)
Biosimilar Initial Advisory	21
BPD Type 1	14
BPD Type 2-4	21

For Biosimilar Initial Advisory and BPD Type 2 meetings, the sponsor may request a written response to its questions, rather than a face-to-face meeting, videoconference or teleconference. If a written response is deemed appropriate, FDA will notify the requester of the date it intends to send the written response. This date will be consistent with the timeframes specified in Table 2 below for the specific meeting type.

b. Performance Goal: FDA will respond to meeting requests and provide notification within the response times noted in Table 1 for 90 percent of each meeting type.

2. Scheduling Meetings

a. Procedure**:** FDA will schedule the meeting on the next available date at which all applicable Center personnel are available to attend, consistent with the component's other business; however, the meeting should be scheduled consistent with the type of meeting requested. Table 2 below indicates the timeframes for FDA to schedule the meeting following receipt of a formal meeting request and background package, or in the case of a written response for Biosimilar Initial Advisory and BPD Type 2 meetings, the timeframes for the Agency to send the written response. If the requested date for any meeting type is greater than the specified timeframe, the meeting date should be within 14 calendar days of the requested date.

Table 2:

Meeting Type	**Meeting Scheduling or Written Response Time**
Biosimilar Initial Advisory	75 calendar days from receipt of meeting request and background package
BPD 2	90 calendar days from receipt of meeting request and background package
	Meeting Scheduling Time
BPD 1	30 calendar days from receipt of meeting request and background package
BPD 3	120 calendar days from receipt of meeting request and background package
BPD 4	60 calendar days from receipt of meeting request and background package

b. Performance goal:

Table 3:

Meeting Type	**Goal**
BPD Type 2	FY 2018-2019: 80% of meetings are held or written responses are sent within the timeframe FY 2020-2022: 90% of meetings are held or written responses are sent within the timeframe

Biosimilar Initial Advisory	90% of meetings are held or written responses are sent within the timeframe
BPD Type 1, 3, and 4	90% of meetings are held within the timeframe for each meeting type

3. <u>Preliminary Responses</u>

a. <u>Procedure</u>**:** The Agency will send preliminary responses to the sponsor's questions contained in the background package no later than five calendar days before the face-to-face, videoconference or teleconference meeting date for BPD Type 2 and Type 3 meetings.

b. <u>Performance goal:</u>

Table 4:

Meeting Type	
BPD Type 2	• FY 2018: 70% of preliminary responses to questions are issued by FDA no later than five calendar days before the meeting date • FY 2019, 75% of preliminary responses to questions are issued by FDA no later than five calendar days before the meeting date • FY 2020, 80% of preliminary responses to questions are issued by FDA no later than five calendar days before the meeting date • FY 2021, 85% of preliminary responses to questions are issued by FDA no later than five calendar days before the meeting date • FY 2022, 90% of preliminary responses to questions are issued by FDA no later than five calendar days before the meeting date

BPD Type 3	90% of preliminary responses to questions are issued by FDA no later than five calendar days before the meeting date

4. Meeting Minutes

a. Procedure**:** The Agency will prepare minutes which will be available to the sponsor 30 calendar days after the meeting. The minutes will clearly outline the important agreements, disagreements, issues for further discussion, and action items from the meeting in bulleted form and need not be in great detail. Meeting minutes are not necessary if the Agency transmits a written response for Biosimilar Initial Advisory and BPD Type 2 meetings.

b. Performance Goal**:** 90% of minutes are issued within 30 calendar days of the date of the meeting.

5. Conditions: For a meeting to qualify for these performance goals:

a. A written request and supporting documentation (i.e., the background package) must be submitted to the appropriate review division or office.

b. The request must provide:

i. A brief statement of the purpose of the meeting, the sponsor's proposal for the type of meeting, and the sponsor's proposal for a face-to-face meeting, teleconference, or for a written response (Biosimilar Initial Advisory and BPD Type 2 meetings only);

ii. A listing of the specific objectives/outcomes the requester expects from the meeting;

iii. A proposed agenda, including estimated times needed for each agenda item;

iv. A list of questions, grouped by discipline. For each question there should be a brief explanation of the context and purpose of the question.

v. A listing of planned external attendees; and

vi. A listing of requested participants/disciplines representative(s) from the Center with an explanation for the request as appropriate.

vii. Suggested dates and times (e.g., morning or afternoon) for the meeting that are within or beyond the appropriate time frame of the meeting type being requested.

c. The Agency concurs that the meeting will serve a useful purpose (i.e., it is not premature or clearly unnecessary). However, requests for BPD Type 2, 3, and 4 Meetings will be honored except in the most unusual circumstances.

The Center may determine that a different type of meeting (i.e., Biosimilar Initial Advisory, or BPD Type 1-4) is more appropriate and it may grant a meeting of a different type than requested, which may require the payment of a biosimilar biological product development fee as described in section 744H of the Federal Food, Drug, and Cosmetic Act before the meeting will be provided. If a biosimilar biological product development fee is required under section 744H, and the sponsor does not pay the fee within the time frame required under section 744H, the meeting will be cancelled. If the sponsor pays the biosimilar biological product development fee after the meeting has been cancelled due to non-payment, the time frame described in section I.I.1.a will be calculated from the date on which FDA received the payment, not the date on which the sponsor originally submitted the meeting request.

Sponsors are encouraged to consult available FDA guidance to obtain further information on recommended meeting procedures.

6. <u>Guidance</u>

a. FDA will publish revised draft guidance on Formal Meetings Between the FDA and Biosimilar Biological Product Sponsors or Applicants no later than September 30, 2018.

b. FDA will update the current draft or final guidance on Best Practices for Communication Between IND Sponsors and FDA During Drug Development, as appropriate, to apply to communications between IND sponsors and FDA during biosimilar biological product development. FDA will publish a revised draft or final guidance by December 31, 2018.

II. ADVANCING DEVELOPMENT OF BIOSIMILAR BIOLOGICAL PRODUCTS THROUGH FURTHER CLARIFICATION OF THE 351(k) REGULATORY PATHWAY

A. On or before December 31, 2017, FDA will publish draft guidance describing considerations for designating biosimilar biological products as interchangeable to

a reference product. FDA will work toward the goal of publishing a revised draft or final guidance within 24 months after the close of the public comment period.

B. On or before December 31, 2017, FDA will publish draft guidance describing statistical considerations for the analysis of analytic similarity data intended to support a demonstration of "highly similar" for biosimilar biological products. FDA will work toward the goal of publishing a revised draft or final guidance within 18 months after the close of the public comment period.

C. On or before March 31, 2019, FDA will publish draft guidance describing processes and further considerations related to post-approval manufacturing changes for biosimilar biological products. FDA will work toward the goal of publishing a revised draft or final guidance within 18 months after the close of the public comment period.

D. FDA will work towards the goal of publishing revised draft guidance or final guidance documents on or before May 31, 2019 for draft guidances published between January 1, 2014 and September 30, 2017, other than those described in (II.A-C). These draft guidances will include:

1. Clinical Pharmacology Data to Support a Demonstration of Biosimilarity to a Reference Product (draft guidance published in May 2014)

2. Nonproprietary Naming of Biological Products (draft guidance published in August 2015)

3. Labeling for Biosimilar Biological Products (draft guidance published in March 2016)

III. ENHANCING CAPACITY FOR BIOSIMILAR REGULATIONS AND GUIDANCE DEVELOPMENT, REVIEWER TRAINING, AND TIMELY COMMUNICATION

A. FDA will strengthen the staff capacity to develop new regulations and guidance to clarify scientific criteria for biosimilar development and approval to provide certainty to industry and other stakeholders related to key regulatory issues including the scope of eligible biosimilar biological products.

B. FDA will strengthen staff capacity to develop or revise MaPPs, SOPPs, and review templates to facilitate rapid update and application of new policies and guidance by review staff, and to develop and deliver timely comprehensive training to all CDER and CBER review staff and special government employees involved in the review of 351(k) BLAs.

C. FDA will strengthen staff capacity to deliver timely information to the public to improve public understanding of biosimilarity and interchangeability.

D. FDA will strengthen staff capacity to deliver information concerning the date of first licensure and the reference product exclusivity expiry date, to be included in the Purple Book.

FDA will update the Purple Book to include the following information: the BLA number, product name, proprietary name, date of licensure, interchangeable or biosimilar determination, and whether the BLA has been withdrawn. FDA will update this information in the Purple Book within 30 days after approval or withdrawal. In addition, within 30 days after FDA determines the date of first licensure, the date of first licensure and the reference product exclusivity expiry date will be included in the Purple Book.

IV. ENHANCING MANAGEMENT OF USER FEE RESOURCES

FDA will establish an independent user fee structure and fee amounts to ensure stable and predictable user fee funding, improve the predictability of FDA funding and sponsor invoices, improve efficiency by simplifying the administration of user fees, and enhance flexibility of financial mechanisms to improve management of BsUFA program funding. FDA is committed to enhancing management of BsUFA resources and ensuring BsUFA user fee resources are administered, allocated, and reported in an efficient and transparent manner. FDA will conduct a series of resource capacity planning and financial transparency activities to enhance management of BsUFA resources in BsUFA II.

A. RESOURCE CAPACITY PLANNING AND MODERNIZED TIME REPORTING

FDA is committed to enhancing management of BsUFA resources in BsUFA II. FDA will conduct activities to develop a resource capacity planning function and modernized time reporting approach in BsUFA II.

1. FDA will publish a resource capacity planning and modernized time reporting implementation plan that includes BsUFA no later than the 2nd quarter of FY 2018. FDA will continue to utilize information and recommendations from a third party assessment of resource capacity planning, financial analytics, and modernized time reporting for BsUFA as part of the implementation plan.

2. FDA will staff a resource capacity planning team that will implement and manage a capacity planning system across the BsUFA program in BsUFA II.

3. FDA will obtain through a contract with an independent accounting or consulting firm an evaluation of options and recommendations for a new methodology to accurately assess changes in the resource and capacity needs of the biosimilar biological product review program. The BsUFA evaluation will be conducted under the same contract and by the same independent accounting or consulting firm that will evaluate options and recommendations for a new methodology to accurately assess changes in the resource and

capacity needs of the human drug review program in PDUFA VI. The report will be published no later than end of FY 2020 for public comment. Upon review of the report and comments, FDA will implement robust methodologies for assessing resource needs of the program. This will include the adoption of a new resource capacity adjustment methodology that accounts for sustained increases in BsUFA workload.

4. FDA recognizes that revenue generated by the capacity adjustment will be allocated to and used by organizational review components engaged in direct review work to enhance resources and expand staff capacity and capability. FDA will document in the annual financial report how the capacity adjustment fee revenues are being utilized.

B. FINANCIAL TRANSPARENCY AND EFFICIENCY

FDA is committed to ensuring BsUFA user fee resources are administered, allocated, and reported in an efficient and transparent manner. FDA will conduct activities to evaluate the financial administration of the BsUFA program to help identify areas to enhance efficiency. FDA will also conduct activities to enhance transparency of BsUFA program resources.

1. FDA will contract with an independent third party to conduct an evaluation of BsUFA program resource management during FY 2018 to ensure that BsUFA user fee resources are administered, allocated, and reported in an efficient and transparent manner in BsUFA II. The BsUFA evaluation will be conducted under the same contract and by the same independent third party that will conduct an evaluation of the PDUFA program resource management. The study will include, but is not limited to, the following areas:

a. Evaluate all components of the BsUFA program resource planning, request, and allocation process from when FDA receives the user fee funds through when funds are spent. The contractor will recommend options to improve the process and data needed to enhance resource management decisions.

b. Assess how FDA administers BsUFA user fees organizationally, including, but not limited to, billing, user fee collection, and execution. The contractor will recommend options to enhance the efficiency of user fee administration.

c. Evaluate FDA's existing BsUFA program financial and administrative oversight and governance functions. Assess alternative governance models including roles and responsibilities, organizational location, and personnel skill sets required. The contractor will recommend options on the most effective governance model to support the biosimilar biological product review program.

d. Assess FDA's technical capabilities to conduct effective financial management and planning in the context of generally accepted government resource management and planning practices. The contractor will recommend options for the technical capabilities needed by financial personnel involved in BsUFA resource management to enhance financial management and planning.

2. FDA will publish a BsUFA five-year financial plan no later than the 2nd quarter of FY 2018. FDA will publish updates to the five-year plan no later than the 2nd quarter of each subsequent fiscal year.

3. FDA will convene a public meeting no later than the third quarter of each fiscal year starting in FY 2019 to discuss the BsUFA five-year financial plan, report on the contribution of the BsUFA spending trigger to the BsUFA program, along with the Agency's progress in implementing modernized time reporting, resource capacity planning, and the modernized user fee structure.

C. MANAGEMENT OF CARRYOVER BALANCE

FDA is committed to reducing the carryover balance to no greater than 21 weeks of the FY 2022 target revenue by the end of FY 2022. However, if FDA is unable to reduce the carryover balance to no greater than 21 weeks during the final year (e.g., over collections in FY 2022 that increase the carryover balance beyond 21 weeks), FDA will (1) outline its plan to reduce the carryover balance to no greater than 21 weeks in the FY 2022 BsUFA financial report and (2) update the BsUFA five-year financial plan.

V. IMPROVING FDA HIRING AND RETENTION OF REVIEW STAFF

To speed and improve development of safe and effective biosimilar biological products for patients, enhancements to the biosimilar biological review program require that FDA hire and retain sufficient numbers and types of technical and scientific experts to efficiently conduct reviews of 351(k) applications. In order to strengthen this core function and increase public access to biosimilar biological products , the FDA will commit to do the following:

A. COMPLETION OF MODERNIZATION OF THE HIRING SYSTEM INFRASTRUCTURE AND AUGMENTATION OF SYSTEM CAPACITY:

1. <u>Complete implementation of FTE-based position management system capability.</u>

a. FDA will complete development of position management baseline accounting of all current positions and FTE counts engaged in the biosimilar biological product review program for each applicable Center and Office including filled and vacant positions, a governance structure

for on-going position management that will be accountable to FDA senior management, and position management policy and guidelines ratified by FDA senior management, outlining processes for adding new positions, deleting positions, and changing established positions.

b. FDA will complete implementation of the new position-based management system.

2. Complete implementation of an online position classification system

a. FDA will finalize the establishment of an online Position Description (PD) library. The library will include all current well-classified PDs and current standardized PDs. Once operational, any new PDs classified using the on-line classification tools, and any newly created standardized PDs, will be stored and accessible within FDA's PD library and available for FDA-wide use as appropriate.

3. Complete implementation of corporate recruiting

a. For key scientific and technical disciplines commonly needed across offices engaged in the biosimilar biological product review program, FDA will complete the transition from the use of individual vacancy announcements for individual offices to expanded use of a common vacancy announcement and certificate of eligible job applicants that can be used by multiple offices. As a part of this effort, FDA will complete the transition from use of individual announcements that are posted for a limited period to common vacancy announcements with open continuous posting to maximize the opportunity for qualified applicants to apply for these positions.

B. AUGMENTATION OF HIRING STAFF CAPACITY AND CAPABILITY

In recognition of the chronic and continuing difficulties of recruiting and retaining sufficient numbers of qualified Human Resources (HR) staff, FDA will engage a qualified contractor to provide continuous support throughout BsUFA II to augment the existing FDA HR staff capacity and capabilities. The utilization of a qualified contractor will assist FDA in successfully accomplishing BsUFA II goals for recruitment and retention of biosimilar biological product review program staff.

C. COMPLETE ESTABLISHMENT OF A DEDICATED FUNCTION TO ENSURE NEEDED SCIENTIFIC STAFFING FOR HUMAN DRUG REVIEW INCLUDING FOR REVIEW OF BIOSIMILAR BIOLOGICAL PRODUCTS

1. Rapid advances in the science and technology of biosimilar biological product development and manufacturing require FDA's biosimilar biological product

review program staff to keep pace with science and learn innovative methods and techniques for review of new therapies. FDA will complete the establishment of a new dedicated unit within the Office of Medical Products and Tobacco charged with the continuous recruiting, staffing, and retention of scientific, technical, and professional staff for the PDUFA and BsUFA review programs.

a. The unit will continuously develop and implement scientific staff hiring strategies and plans, working closely with the center review offices and the FDA HR office, to meet discipline-specific hiring commitments and other targeted staffing needs. It will function as a scientific-focused recruiter conducting ongoing proactive outreach to source qualified candidates, and conducting competitive recruiting to fill vacancies that require top scientific, technical, and professional talent.

b. The unit will conduct analyses, no less than annually, of compensation and other factors affecting retention of key staff in targeted disciplines and provide leadership and support for agency compensation oversight boards that currently exist or may be established as needed to ensure retention of key scientific, technical, and professional staff.

D. SET CLEAR GOALS FOR BIOSIMILAR BIOLOGICAL PRODUCT REVIEW PROGRAM HIRING

1. FDA will establish priorities for management of the metric goals for targeted hires within the biosimilar biological product review program staff for BsUFA II. In particular, FDA will target hiring 15 FTE in FY 2018, to enhance capacity for biosimilar guidance development, reviewer training, and timely communication.

2. FDA will confirm progress in the hiring of BsUFA I FTEs. FDA will report on progress against the hiring goal for BsUFA II on a quarterly basis posting updates to the FDA website BsUFA Performance webpage.

E. COMPREHENSIVE AND CONTINUOUS ASSESSMENT OF HIRING AND RETENTION

FDA hiring and retention of staff for the biosimilar biological product review program will be evaluated by a qualified, independent contractor with expertise in assessing HR operations and transformation. The BsUFA II assessment will be conducted under the same contract and by the same independent contractor that will conduct the assessment related to hiring and retention of staff for the human drug review program in PDUFA VI. It will include continuous assessments throughout the course of implementation of the performance initiatives identified in Sections V.A-D, and metrics including, but not limited to, those related to recruiting and retention in the PDUFA and BsUFA review programs including, but not limited to, specifically targeted scientific disciplines and levels of

experience. The contractor will conduct a comprehensive review of current hiring processes and hiring staff capacity and capabilities that contribute to achievement of successes, potential problems, or delays in PDUFA or BsUFA review program staff hiring. This includes the entire hiring function and related capabilities. FDA and regulated industry leadership will periodically and regularly assess the progress of hiring and retention throughout BsUFA II.

1. **Initial Assessment:** The assessment will include an initial baseline assessment to be conducted and completed no later than December 31, 2017. The initial baseline study will include an evaluation of the current state and provide recommended options to address any identified gaps or areas identified as priorities for improvement, and a study report to be published no later than December 31, 2017. FDA will hold a public meeting no later than December 31, 2017, to present and discuss report findings, and present its specific plans, including agency senior management oversight, and timeline for implementing recommended enhancements to be fully operational by no later than December 31, 2018.

2. **Interim Assessment:** An interim assessment will be published by March 31, 2020, for public comment. By June 30, 2020, FDA will hold a public meeting during which the public may present their views. FDA will discuss the findings of the interim assessment, including progress relative to program milestones and metrics, and other aggregated feedback from internal customers and participants in HR services that may be included in the continuous assessment. FDA will also address any issues identified to date including actions proposed to improve the likelihood of success of the program.

3. **Final Assessment:** A final assessment will be published by December 31, 2021, for public comment. FDA will hold a public meeting by no later than March 30, 2022, during which the public may present their views. FDA will discuss the findings of the final assessment, including progress relative to program milestones and metrics, and other aggregated feedback from internal customers and participants in HR services that may be included in the continuous assessment. FDA will also address any issues identified and plans for addressing these issues.

VI. DEFINITIONS AND EXPLANATION OF TERMS

A. The term "review and act on" means the issuance of a complete action letter after the complete review of a filed complete application. The action letter, if it is not an approval, will set forth in detail the specific deficiencies and, where appropriate, the actions necessary to place the application in condition for approval.

B. A resubmitted original application is a complete response to an action letter addressing all identified deficiencies.